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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,551	08/07/2006	Stig Ollmar	P08984US01/BAS	8295

881 7590 03/31/2009
STITES & HARBISON PLLC
1199 NORTH FAIRFAX STREET
SUITE 900
ALEXANDRIA, VA 22314

EXAMINER

D'ANGELO, MICHAEL J

ART UNIT	PAPER NUMBER
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3735

MAIL DATE	DELIVERY MODE
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03/31/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/588,551	Applicant(s) OLLMAR ET AL.	
	Examiner MICHAEL D'ANGELO	Art Unit 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 47-93 is/are pending in the application.
- 4a) Of the above claim(s) 47-78 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 79-93 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/23/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group II, claims 79-93, in the reply filed on March 19, 2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Specification

2. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 79-93 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claim 79 recites the limitation "for monitoring glucose in a body fluid of a subject according to the method of claim 47" at lines 1-2. Although this limitation is an intended use limitation in the preamble, claim 47 has been withdrawn from consideration in view of the Response to the Restriction Requirement filed March 19, 2009. Accordingly, the metes and bounds of this limitation are unclear.

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6. Claim 79 recites the limitations "the first body tissue" at lines 3-4, "the second body tissue" at lines 6-7, and "the means for measuring impedance" at line 8. There is insufficient antecedent basis for these limitations in the claim.

Claim Rejections - 35 USC § 101

7. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

8. Claims 79-93 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 79 recites "said electrodes are in electrically conductive contact with the first body tissue or the second body tissue." Claim 92 recites "the apparatus is implanted in the body tissue." These limitations recite a positive relationship to the human body. However, the human body is non-statutory subject matter and cannot be positively recited. Therefore, applicant should amend claim 79 to recite --said electrodes are adapted for electrically conductive contact...-- and claim 92 to recite --the apparatus is adapted to be implanted in the body tissue--.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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10. Claims 79-85 and 88-89 and 91-93 rejected under 35 U.S.C. 102(e) as being anticipated by Steil et al. (US 2003/0130616).

11. **Regarding claim 79**, Steil discloses an apparatus for monitoring glucose in a body fluid of a subject according to the method of claim 47 (paragraphs 319 and 320), the apparatus comprising: at least one pair of an injection electrode and sensing electrode (working electrode and counter electrode, paragraph 319, lines 1-11), said electrodes are in electrically conductive contact with the first body tissue (view figure 4), a microprocessor operatively connected to the means for measuring impedance for determining the amount of glucose in the body fluid based upon the impedance measurements (controller-12, view figure 1, paragraph 319, line 8 and paragraph 320, lines 8-11).

12. **Regarding claims 80-82**, Steil discloses one pair of electrodes (view figure 3, working and counter electrode), two pairs of electrodes (paragraph 321, lines 1-3, view figure 2), and that the first body tissue is a sub-dermal tissue (paragraph 318, lines 1-4).

13. **Regarding claims 83-85**, the claims are directed to the intended use of the apparatus merely defining the particular type of sub-dermal tissue contacting the electrodes. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The apparatus of Steil is capable of contacting the claimed sub-dermal tissues.

14. **Regarding claims 88-89 and 91-93**, Steil discloses that the microprocessor is operatively connected to an insulin pump and includes means to adjust the amount of insulin flow via the pump to the subject based on the determined glucose level (abstract, view figure 1, paragraph 98,

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lines 30-35), a means for calibrating the apparatus against a directly measured glucose level (paragraph 248, lines 1-8, view figure 32), an indicator comprising a visual display connected to the processor for indicating the determined amount of glucose (paragraph 240), and the apparatus is implanted in the body tissue for which the impedance is to be measured (paragraph 318, lines 1-4).

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

16. A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. Claim 86 is rejected under 35 U.S.C. 103(a) as being unpatentable over Steil et al. (US 2003/0130616) as applied to claim 79 above, and further in view of Purvis et al. (US 2004/0182719).

18. **Regarding claim 86**, Steil discloses a source of electrical current connected to the injection electrodes (view figure 7), but fails to disclose an amperometer or a voltmeter, wherein the amperometer and current source are connected to the injection electrodes and the voltmeter is connected to the sensing electrodes.

19. However, Purvis discloses an amperometer and a voltmeter (paragraph 5, lines 9-11 and paragraph 12, lines 1-4), wherein the amperometer and current source are connected to the injection electrodes and the voltmeter is connected to the sensing electrodes (paragraph 5, lines 9-11 and paragraph 12, lines 1-4).

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20. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the sensor of Steil to include an amperometer and a voltmeter, wherein the amperometer and current source are connected to the injection electrodes and the voltmeter is connected to the sensing electrodes, as taught by Purvis, in order to control the voltage and sense the voltage/current.

21. Claim 87 is rejected under 35 U.S.C. 103(a) as being unpatentable over Steil et al. (US 2003/0130616) in view of Purvis et al. (US 2004/ 0182719) and further in view of Elden et al. (US 6,517,482)

22. **Regarding claim 87**, Steil's invention as modified by Purvis discloses all of the claim limitations above except for having an electrical current at a plurality of frequencies in a range of 1Hz to 10MHz.

23. However, Elden discloses an electrical current at a plurality of frequencies in a range of 1Hz to 10MHz (claim 1).

24. It would have been obvious to one of ordinary skill in the art at the time applicant's invention was made to provide a glucose monitoring system similar to that of Steil, as modified by Purvis, with an electrical current at a plurality of frequencies in a range of 1Hz to 10MHz as taught by Elden in order to accurately correlate impedance measurements with glucose levels.

25. Claim 90 is rejected under 35 U.S.C. 103(a) as being unpatentable over Steil et al. (US 2003/0130616) in view of Abreu (US 2002/0049389).

26. **Regarding claim 90**, Steil fails to disclose that the processor is programmed to determine the glucose level based on a principal component analysis and a partial least square regression analysis.

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27. However, Abreu discloses a processor programmed to determine the glucose level based on a principal component analysis and a partial least square regression analysis (paragraph 296, lines 6-8.

28. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the processor of Steil to determine the glucose level based on a principal component analysis and a partial least square regression analysis as taught by Abreu in order to reduce variability due to tissue structure.

Conclusion

29. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 5,036,861, WO 9,420,602, US 5,353,802, and US 5,771,891 are directed toward glucose sensors and methods of use using electrical impedance. Mastrototaro et al. (US 6,424,847) discloses a glucose sensor for use in muscles, vessels, and other tissue types.

30. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL D'ANGELO whose telephone number is (571) 270-7112. The examiner can normally be reached on Monday-friday 9-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Charles A. Marmor, II/
Supervisory Patent Examiner
Art Unit 3735

/MD/
Examiner, Art Unit 3735